

## REMARKS

Claims 16, 19-40, 44 and 45 are pending in the application; claims 31-40 are withdrawn.

### Rejection under 35 U.S.C. 112

In regard to the rejection under 35 USC 112, applicant has adopted examiner's suggestion and has included the claim language "and composites thereof".

Reconsideration and withdrawal of the rejection of the claims under 35 USC 112 are respectfully requested.

### Rejection under 35 U.S.C. 103

Examiner has referred in the final rejection to the rejections made in prior office actions; the prior office dated 1/6/2009 states that claims 16, 19-24, 30, 44, 45 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Langer et al.* (US 6,224,893).

Claim 16 has been amended to include an additional feature relating to the fibers: the fibers are arranged by electrostatic flocking on the at least one side substantially perpendicular to a surface of said at least one side.

The advantages of the electrostatic flocking process are discussed in the present application on page 2, last paragraph:

*"Through the electrostatic flocking the fibers are **arranged almost perpendicularly on the surface of the base material**. Advantageously, the **high fiber pull-out resistance achieved through electrostatic flocking** prevents the detachment of the fibers from the base material. Advantageously, the **scaffold according to the invention provides an elastic growth lattice, which is stable against compression**, for cell colonization in vitro or the ingrowth of cells in vivo. Together with the base material, the **fibers take on the function of the extra-cellular matrix** which occurs in natural tissue. For this purpose, the fiber density of over 100 fibers /mm<sup>2</sup>, preferably 150 to 500 fibers /mm<sup>2</sup>, is very high compared to flocked structures which are known from other technological areas."*

The second paragraph of page 3 of the instant specification explains the high compressive strength and module of the scaffold that is achieved by the flocked fibers:

*"The high compressive strength ( $\sigma_D$  over 0.1 MPa, linear elastic behavior), and the high compressive module ( $E$  over 0.2 MPa) of the scaffold **are achieved through the almost perpendicular alignment of the fibers** and the high flocking density. The attainable flocking density is the higher the shorter the fibers used for flocking are. With fibers that are 1 mm long it is preferably 150 to 250 fibers/mm<sup>2</sup>, with fibers that are 0.5 mm long it is preferably 300 to 400 fibers/mm<sup>2</sup>.*

*The denser the flocking and the shorter the fibers, the less the fibers can buckle laterally under pressure, since they are prevented from doing so by the neighboring fibers."*

It is respectfully submitted that the perpendicular arrangement of the fibers is possible only by electrostatic flocking. By electrostatic flocking the fibers are individually attached upright to the substrate surface in perpendicular arrangement (see e.g. Fig. 1 and Fig. 2). The fibers are essentially parallel to one another (see also Fig. 4 – raster electron micrograph of the scaffold and corresponding description on page 14, 2<sup>nd</sup> full paragraph:

*" ... Fig. 4 shows that, through the electrostatic flocking, nearly all fibers 3 are arranged in an ordered, almost perpendicular orientation to the surface of the base material 1....".*

Therefore, the electrostatic flocking process imparts a structural feature to the scaffold material in that the fibers are positioned in perpendicular orientation on the surface. This arrangement provides compression resistance and a growth lattice for cell colonization as explained in the above cited text portions of the specification.

As regards examiner's statement in the last office action that applicant's arguments miss the mark because, in examiner's words, "the three-dimensional body and connected fibers are structural limitations and do not change the composition as claimed", it is respectfully submitted that what is claimed is a STRUCTURE and not a composition. The claim is directed to a SCAFFOLD and the SCAFFOLD is comprised of

a base material and fibers connected to the base material. See Fig. 4 of the instant application showing the claimed structure. The fact that the claims sets forth certain compounds of which the base material and the fibers are made does not make the claimed subject matter a COMPOUND that is defined only by its composition.

Claim 16 as amended and the dependent claims are therefore believed to be allowable.

Reconsideration and withdrawal of the rejection of the claims under 35 USC 103 are respectfully requested.

#### **Claims 25-29**

It is again pointed out that the claims 25-29 do not stand rejected over prior art.

In the office action dated 12/28/2007 examiner stated that claims 20-25, 28, 29 are OBJECTED as depending on a rejected base claim, indicating allowability of the claims.

Claims 25, 28, 29 were rewritten in independent form on 3/28/2008.

In the office action dated 7/1/2008 the claims 16, 19-30 were rejected under 35 USC 112 because of the language "collagen, collagen derivatives ...." and "composites". No prior art rejection was set forth in this office action. The rewritten claims 25, 28, 29 in independent form do not include the language rejected under 35 USC 112 so that the rejection made in this office action does not apply to claims 25-29.

In the office action dated 1/6/2009 examiner has repeated the 112 rejection against claims 16, 19-30 and applied it also to new claims 44-45.

Applicant has pointed out in amendment dated 4/6/2009 that the rejection under 112 does not apply to claims 20, 21, 25-30 because these claims do not contain the claim language that examiner has rejected.

The office action dated 7/13/09 refers to the prior actions for the specifics of the rejections, i.e., the prior office action dated 1/6/2009. The examiner has ignored applicant's prior remarks submitted with the amendment dated 4/6/2009 and still ignores the fact that the claims 20, 21, 25-30 do not include the rejected claim language. This office action again does not reject claims 25-29 over prior art.

**Therefore, claims 25-29 DO NOT STAND REJECTED and should be allowable.**

### **CONCLUSION**

In view of the foregoing, it is submitted that this application is now in condition for allowance and such allowance is respectfully solicited.

Should the Examiner have any further objections or suggestions, the undersigned would appreciate a phone call or **e-mail** from the examiner to discuss appropriate amendments to place the application into condition for allowance.

Authorization is herewith given to charge any fees or any shortages in any fees required during prosecution of this application and not paid by other means to Patent and Trademark Office deposit account 50-1199.

Respectfully submitted on Oktober 24, 2009,

/Gudrun E. Hockett/

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